510(k) SUMMARY

FEB 2 8 2003

SUBMITTER: **Rockwell Medical, Technologies, Inc.**
30142 Wixom Road
Wixom, MI 48393
Phone: 248-960-9009

DATE PREPARED: **November 25th, 2002**

DEVICE NAME: **Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate**

CLASSIFICATION NAMES: **Concentrate Solutions for Hemodialysis**
Accessories to Hemodialysis

PREDICATE DEVICE: **Rockwell Medical Dri-Sate Acid Concentrate Solutions and Powders**
Fresenius USA, Inc. Granuflo Dialysate Concentrate

Device Description:

The Rockwell Medical Technologies, Inc. Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate contain, water, salt, dextrose, and non-sugar electrolytes formulated and intended for use in hemodialysis when mixed or proportioned with the appropriate volume of purified water and bicarbonate concentrate solution. These concentrate solutions, when proportioned/ mixed in a three-stream dialysis machine with pre-treated or purified water meeting or exceeding AAMI Standards and a bicarbonate concentrate solution, may be used in conventional and commercially available hemodialysis machines or monitors as a hemodialysis solution. The Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate presented in this 510K Notification are intended to be used in three stream hemodialysis machines in which an acidified concentrate is proportioned into one stream, a bicarbonate, chloride and sodium concentrate solution is proportioned into the second stream of the hemodialysis machine, and water is proportioned into the third stream. These three streams are then mixed to prepare a final proportioned hemodialysis solution. These types of final hemodialysis solutions are commonly referred to as "Bicarbonate Hemodialysis Solutions." These proportioned hemodialysis solutions are then heated to body temperature and then perfused through the dialysis fluid compartment of artificial kidneys or hemodialyzers. These bicarbonate hemodialysis solutions are separated from the patient's blood by means of a semi-permeable cellulosic or non-cellulosic membrane which serves as a molecular weight selective barrier to the passage of molecules beyond a certain molecular weight. The molecular weigh cut-off of each type of membrane may vary depending on the membrane type, manufacturing process, etc. The semi-permeable membrane in a hemodialyzer permits the passage of smaller molecular weight (less than 5,000 Daltons for conventional cellulosic membranes), ionized and non-ionized molecules, waste products and toxins (i.e. blood urea nitrogen, creatinine, potassium, etc.) contained in the patient's blood circulating through the dialyzer, to pass through the semi-permeable membrane into the bicarbonate hemodialysis solutions, exit the hemodialyzer, enter the hemodialysis monitor and exit the monitor and are ultimately discarded. The ionic and molecular composition of the hemodialysis solution establishes the concentration gradient between the blood and the hemodialysis solution passing through the hemodialyzer which permits the effective removal of waste products and toxins found in excess in the patient's blood during acute and end-stage renal failure.

Since different patients have different requirements for the removal rates and quantities of various molecules and toxins (i.e. blood urea nitrogen, creatinine, potassium, phosphate, magnesium, chloride, sodium calcium water, etc.) in acute and chronic renal failure, it necessitates having a variety of different bicarbonate containing hemodialysis solutions to satisfy the needs of all acute and end-stage renal failure patients. In addition, there a number of different types of hemodialysis machines which have different proportioning rates. The concentrate mixes and solutions presented in this 510K Notification are designed

or formulated to be used with hemodialysis machines that proportion according to the following dilution ratios:

TABLE I

Stream 1	Stream 2 Acidified Concentrate Proportioning Ratios	Stream 3: Bicarbonate Concentrate Proportioning Ratios
Water	**1:35.83 or 1:44.00 or 1:34.00**	**1:19.13 or 1:27.57 or 1:25.16**

It is for these reasons that a manufacturer of these hemodialysis concentrate solutions and must provide a number of different formulations to contain varying concentrations of the various molecular weight components. The concentrations of these various molecular components are varied in the final hemodialysis solution within physiological and non-physiological ranges to permit the efficient removal of lack thereof from the patient's blood during hemodialysis.

Predicate Devices:
The Rockwell Medical Technologies, Inc. Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate are substantially equivalent to the Rockwell Medical Acid concentrate solutions for bicarbonate hemodialysis as well as the Fresenius USA, Inc., Granuflo/Granulate Powder Dialysate Concentrates.

Intended Use:

Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate Indications:

The Rockwell Medical Technologies, Inc., Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/ monitor and bicarbonate concentrate

This indication statement is essentially the same as the indication statement for the predicate device.

Technological Characteristics:

Comparing the proposed device to the predicate device, both devices utilize the same range of chemical compositions, packaging and formulations. There are no significant differences.

Summary of Non-Clinical Tests:

In vitro testing was performed to determine the chemical composition and range of composition.. The results of these tests confirmed that the proposed device is equivalent to the proposed device for these parameters.

Clinical Test Results:

Clinical testing was not performed

Conclusions:

Testing performed on the Rockwell Medical Technologies, Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate Inc. indicates that they are safe, effective, and performs as well as the predicate device, when used in accordance with the instructions for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2003

Mr. Gerry Fritz
Director of Quality Assurance
& Operations
Rockwell Medical Technologies, Inc.
30142 Wixom Road
WIXOM MI 48393

Re: K023985
Trade/Device Name: Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis system and accessories
Regulatory Class: II
Product Code: 78 KPO
Dated: November 25, 2002
Received: December 2, 2002

Dear Mr. Fritz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER (IF *KNOWN*): K023985

DEVICE NAME: Rockwell Medical Technologies, Inc., Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate

INDICATIONS FOR USE:

Indications for Use Statement

The Rockwell Medical Technologies, Inc., Acidified Component Concentrates for Bicarbonate Dialysis Containing Di-Acetate are indicated for use in acute and chronic hemodialysis and to be used with the appropriate hemodialysis machine/ monitor and bicarbonate concentrate

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation **(ODE)**

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use_____
(Optional Format 1-2-96)

David A. Lyon

(Division Sign-Off)
Division **of Reproductive, Abdominal,**
and Radiological Devices
510(k) Number K023985